

HIGHLY CONFIDENTIAL: SUBJECT TO PROTECTIVE ORDER

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO EASTERN DIVISION**

IN RE NATIONAL PRESCRIPTION
OPIATE LITIGATION

County of Summit, Ohio, et al.

v.

Purdue Pharma L.P., et al.

The County of Cuyahoga

v.

Purdue Pharma L.P., et al.

CASE NO. 1:17-MD-2804

JUDGE POLSTER

TRACK ONE CASES

SUPPLEMENTAL EXPERT REPORT OF PROFESSOR MARGARET K. KYLE

June 27, 2019

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I. Scope of charge and summary of opinions

I.A. Scope of charge

- (1) On May 10, 2019, I submitted an expert report on behalf of Defendant Allergan in the matter captioned above.¹ In that report I explained that I had not yet received all of the materials supporting the reports of Plaintiffs' experts Dr. Craig McCann and Ms. Lacey Keller, and I explained my scope of charge with respect to Dr. McCann and Ms. Keller, as follows:

I have also been asked to review the expert reports of Dr. Craig McCann and Ms. Lacey Keller to evaluate whether they have correctly identified transactions associated with Allergan products. Based on my review of the materials Dr. McCann provided on April 15, it appears that he is inappropriately assigning transactions to both Actavis and to Allergan, which results in duplicating those attributed to Allergan. As of the date of this report, I have been unable to completely replicate Dr. McCann's analysis because of the late production of his backup materials. In particular, Dr. McCann's materials were not produced by Plaintiffs' counsel with his report, and his materials were still being provided as late as May 6. I am still assessing whether the provided backup materials are complete. Thus, I reserve the right to issue a supplement with this analysis. Based on my review of Ms. Keller's report, she does not attribute to Allergan any transactions that exceed the compliance metrics used in her report. In the event that Ms. Keller supplements her report at a later date and this conclusion changes, I reserve the right to supplement my report to address these new allegations.²

- (2) I have since reviewed Dr. McCann's production of backup materials received on May 6, 2019, as well as his deposition taken on May 9 and 10, 2019, and confirmed that he does not correctly identify Allergan products. I have also reviewed materials related to Ms. Keller's opinions. These materials include the "Expert Analysis – Addendum" report submitted by Ms. Keller on May 11, 2019; the reliance files provided by Ms. Keller on May 29, 2019, and Ms. Keller's deposition taken on June 13, 2019.

¹ Because I have previously discussed my retention and qualifications, including in Appendix A of my May 10 Report, I will not repeat them here. I incorporate by reference all predefined terms, as well as the materials cited in Appendix B of my May 10 Report. A list of the additional materials that I have considered in the preparation of this supplemental report is contained in Appendix A. Expert Report of Professor Margaret K. Kyle, May 10, 2019, Appendix A.

² Expert Report of Professor Margaret K. Kyle, May 10, 2019 ¶ 6, footnote 4.

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- (3) Counsel for Allergan have asked me to apply my expertise with respect to data analytics, which is integral to much of my economic research, to:
- Assess whether and to what extent Dr. McCann inappropriately attributed ARCOS transactions to Allergan;
 - Evaluate whether the ARCOS transactions analyzed by Dr. McCann, after limiting to the transactions correctly attributed to Allergan, appear in the chargeback data analyzed by Ms. Keller;
 - Summarize each of the Allergan chargeback transactions analyzed by Ms. Keller, which are included in her recently provided backup materials but only referenced in aggregate in her report; and
 - Quantify the number of Allergan transactions analyzed by Dr. McCann in Cuyahoga and Summit counties as a percentage of all ARCOS transactions for Allergan products nationally.
- (4) I reserve the right to update my opinions if new information or materials become available during the course of this litigation (e.g., claims data). If I am called upon to testify at trial, I also reserve the right to employ demonstrative exhibits that summarize facts or opinions that are disclosed in this report, in my backup materials, or in new information that subsequently becomes available.

I.B. Summary of opinions

- (5) Based on my review of the recently produced McCann and Keller backup materials, I have determined the following:
- Dr. McCann's analysis of ARCOS data inappropriately attributes other manufacturers' products to Allergan. Correcting for the inappropriately assigned products reduces the number of Dr. McCann's analyzed Allergan transactions by more than [REDACTED]
 - [REDACTED]. Further, no more than [REDACTED] of all Allergan transactions analyzed by Dr. McCann appear in the chargeback data produced by Allergan and analyzed by Ms. Keller. This is not surprising because Allergan's opioid products are branded products that, like most branded products, are typically not discounted to indirect purchasers. Chargebacks are not generated in the absence of such discounting.³
 - Ms. Keller's reliance materials reveal that her metrics "flag" a total of four specific Allergan chargeback transactions. These four chargeback transactions are all for Norco; there are no

³ See, e.g., "Follow the Pill: Understanding the U.S. Commercial Pharmaceutical Supply Chain," Prepared for The Kaiser Family Foundation by: The Health Strategies Consultancy LLC, March 2005.

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flagged chargebacks for any other Allergan products. In Section II.C, I summarize the specific transactions analyzed and flagged by Ms. Keller and provide additional context about these transactions based on the information contained in her recently produced materials.

- For products correctly assigned to Allergan, the ARCOS transactions in Cuyahoga and Summit counties account for only [REDACTED] of the total number of ARCOS transactions for these products nationally.

II. Analysis of Dr. McCann's and Ms. Keller's recently produced materials

II.A. Correcting Dr. McCann's identification of Allergan products reduces the number of Allergan ARCOS transactions he analyzes by more than [REDACTED]

- (6) Dr. McCann's April 15, 2019 report assigns ARCOS transactions for a product to all manufacturers that meet any of his three criteria:
- the 5-digit labeler code of the product was associated with the manufacturer in May 2018;⁴
 - the manufacturer appears as the original source of the product in ARCOS data (including when they are the contract manufacturer for another manufacturer);⁵ or
 - the product appears at least once in chargeback data that Dr. McCann associates with the manufacturer.⁶

However, these criteria result in Dr. McCann inappropriately attributing to Allergan a large number of ARCOS transactions that are associated with non-Allergan products, including a large number of Actavis generic opioids that satisfy Dr. McCann's faulty chargeback data criterion.⁷ Also, once Dr. McCann attributes a product to a manufacturer, he incorrectly assumes that the manufacturer had ownership of the product for the entire period of data he analyzes. In Figure 1, I summarize all ARCOS transactions Dr. McCann analyzes, the transactions Dr. McCann attributes to Allergan, and the transactions actually associated with Allergan products during the periods identified in Section II.B of my May 10 report.⁸ Limiting Dr. McCann's data to Allergan products reduces the number of transactions he attributes to Allergan from [REDACTED]—a reduction of more than [REDACTED]. In Figure 2, I present additional detail on the number of transactions associated with each product.

⁴ Second Supplemental Expert Report of Craig J. McCann, Ph.D., CFA, April 15, 2019 [hereinafter "McCann Manufacturer Report"] ¶¶ 10–14, 21–22; Deposition of Craig J. McCann, May 10, 2019 [hereinafter "McCann May 10 Dep."] at 658:24–661:3.

⁵ McCann Manufacturer Report ¶¶ 15–17, 21, 23; McCann May 10 Dep. at 697:15–699:20.

⁶ McCann Manufacturer Report ¶¶ 18–19, 21.

⁷ McCann May 10 Dep. at 737:1–739:4.

Lines 379–585 of Dr. McCann's "Manufacturer NDC.do" program indicate that products he assigns to Allergan are drawn in part from files he describes as "Teva (Allergan)" that are contained within a folder titled "Documents Received\Chargeback data\Teva\Files\Allergan" (emphasis added) and include files with an "Acquired_Actavis" Bates stamp in addition to those with an "Allergan" Bates stamp.

⁸ These products include Kadian 2009–present, Norco, Combunox, Maxidone, Reprexain January 2004–February 2007, and Lorcet [REDACTED]. Expert Report of Professor Margaret K. Kyle, May 10, 2019, Section II.B.

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Figure 1. ARCOS transactions analyzed by Dr. McCann as Allergan products

Calculation	ARCOS transactions	NDCs	Brands/ molecules	Average monthly dosage units per pharmacy
All transactions McCann analyzes				
Products McCann attributes to Allergan				
Allergan products				

Source: McCann backup data.

Figure 2. ARCOS transactions analyzed by Dr. McCann as Allergan products, by product

Brands/molecules	Transactions McCann attributes to Allergan	Transactions of Allergan products	Average monthly dosage units per pharmacy
HYDROCODONE-ACETAMINOPHEN			
OXYCODONE-ACETAMINOPHEN			
FENTANYL/NS			
HYDROMET			
OXYCODONE HCL			
MORPHINE SULF			
KADIAN			
HYCD/IBUPROFEN			
OXYCODONE W/ASPIRIN			
ASPIRIN/CD			
MORPHINE SULFATE ER			
NORCO			
OXYMORPHONE HCL ER			
FENTANYL CIT			
COMBUNOX			
APAP/CD			
OXYCODONE/IBUPROF			
MAXIDONE			
HYDROMORPHONE HCL ER			
CODEINE			
REPREXAIN			
Total			

Source: McCann backup.

Note: Average dosage units exclude transactions with 0 or negative dosage units, which include products with liquid formulations such as hydromet and certain codeine products.

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- (7) As shown in Figure 1, the ARCOS transactions appropriately attributed to Allergan account for only [REDACTED] of all transactions, and the monthly dosage units per pharmacy actually associated with Allergan products are [REDACTED] lower than for all transactions and [REDACTED] lower than for the transactions Dr. McCann attributes inappropriately to Allergan. For Allergan's products, the average number of monthly dosage units per pharmacy equates to just a few prescriptions. For Kadian, for example, the average number of monthly dosage units per pharmacy amounts to approximately 5 prescriptions based on the number of dosage units per prescription I observe in the IQVIA data. For Norco, the average number of monthly dosage units per pharmacy amounts to less than 4 prescriptions. Given such a low number of monthly prescriptions per pharmacy, even small deviations in the volume of pharmacy purchases could trigger Dr. McCann's metrics.

II.B. The ARCOS transactions flagged by Dr. McCann were not sold by Allergan and do not appear in Ms. Keller's chargeback data analysis

- (8) I have also reviewed the transactions analyzed by Dr. McCann after limiting to the transactions appropriately attributed to Allergan, [REDACTED]
[REDACTED]
- (9) I also understand that Mr. Karl Colder has explained that Allergan did not have access to the ARCOS data analyzed by Dr. McCann and only had access to its own chargeback data. I have compared Allergan's chargeback data analyzed by Ms. Keller to the ARCOS data analyzed by Dr. McCann and find that Allergan's chargeback data capture at most [REDACTED] of transactions in Cuyahoga and Summit counties and [REDACTED] nationally. This is not unexpected: Allergan's opioid products are branded products that, like most branded products, are typically not discounted to indirect purchasers such as small independent pharmacies. Chargebacks are only generated in instances in which a wholesaler or distributor purchases a product at list price and sells to a downstream pharmacy at a discounted price pursuant to an agreement between the manufacturer and the pharmacy (or the buying group in which the pharmacy participates).⁹ Allergan routinely sold its opioid products to wholesalers and distributors at list price without any agreement with downstream pharmacies.
- (10) Figure 3 presents the number of Kadian and Norco chargeback transactions as a percentage of total retail ARCOS Kadian and Norco transactions by year and product for Cuyahoga and Summit counties.¹⁰ Figure 4 presents the number of Kadian and Norco chargeback transactions as a percentage of total retail ARCOS Kadian and Norco transactions by year and product nationally. I

⁹ See, e.g., "Follow the Pill: Understanding the U.S. Commercial Pharmaceutical Supply Chain," Prepared for The Kaiser Family Foundation by: The Health Strategies Consultancy LLC, March 2005.

¹⁰ As in my May 10 report, I have been asked by counsel to assume products other than Kadian and Norco are not the subject of Plaintiffs' allegations and have not included them in my analyses in the body of this report. Nevertheless, I also ran alternative versions of my analyses that included these additional drugs and determined that they do not materially impact my analyses or conclusions. I include these analyses in my backup data.

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have not attempted to match individual chargeback transactions to ARCOS transactions; if any chargebacks are not reflected in the retail ARCOS data (e.g., if they reflect non-retail transactions), these percentages would be overstated.

Figure 3. Kadian and Norco chargeback transactions in Keller data as a percent of total ARCOS transactions in McCann data appropriately attributed to Allergan, Cuyahoga and Summit counties

Year	Kadian	Norco	Total

Source: McCann ARCOS data, 2006–2014; Keller Allergan chargeback data, 2006–2014.

Figure 4. Kadian and Norco chargeback transactions in Keller data as a percent of total ARCOS transactions in McCann data appropriately attributed to Allergan, national

Year	Kadian	Norco	Total

Source: McCann ARCOS data, 2006–2014; Keller Allergan chargeback data, 2006–2014.

II.C. Allergan chargebacks analyzed and flagged by Ms. Keller

- (11) In Figure 5, I summarize the Allergan chargebacks (which pertain only to a single product, Norco) in Cuyahoga and Summit counties to pharmacies with transactions that are flagged by Ms. Keller. In

addition to the fields present in Ms. Keller's data, I estimate the number of Norco prescriptions that each order would fill based on the average number of pills per prescription present in the IQVIA data that I rely on in my May 10 Report. The IQVIA data indicate an average of roughly 99 Norco pills per prescription at the time of these chargebacks. Because each Norco package in Figure 5 is made up of 100 dosage units, one Norco package equates to, on average, one prescription.¹¹

(12) Ms. Keller flags four chargeback transactions, which are reflected in Figure 5:

- An August 28, 2005 chargeback for a shipment of 6 Norco packages to a CVS store in Stow. This transaction is identified by Ms. Keller as double the national average of Allergan hydrocodone chargebacks.¹² This is the only chargeback for this store that is found in the Allergan chargeback data for the entire time period analyzed by Ms. Keller, and the total of 600 Norco dosage units would fill an average of 6 prescriptions.
- Three chargebacks for Norco shipments to a CVS store (at the time Revco Discount Drug Center) in Akron. In addition to Ms. Keller's flagged chargebacks, the data show two other chargebacks of Norco to the same store, for a total of five chargebacks.
 - The first chargeback, on September 19, 2004, reflects 2 Norco packages totaling 200 dosage units, which would fill an average of 2 prescriptions. This chargeback was not flagged.
 - The second chargeback, on September 20, 2004, reflects 1 Norco package totaling 100 dosage units, which would fill an average of 1 prescription. This chargeback was not flagged.
 - The third chargeback, on September 12, 2005, reflects 2 Norco packages totaling 200 dosage units, which would fill an average of 2 prescriptions. This chargeback was flagged by Ms. Keller's "Actavis (Teva): 125% Order Average" metric, which is triggered by "any buyer that placed a single order that was 125% of their previous six-month average per order of a specific NDC."¹³
 - This chargeback does not appear to meet the criteria described in Ms. Keller's report, as there are no chargebacks for this buyer in the previous six months. It is possible this chargeback was flagged in error by comparison to the September 2004 chargebacks, which occurred one year prior. If so, this chargeback would have been flagged because the 200 dosage units on the flagged order was more than 125% of the 150 *average* dosage units of the two previously described September 2004 orders, despite the total of 200

¹¹ If instead one were to assume the "[t]otal MMEs consumed for appropriate treatment" as described by Professor Rosenthal in her report, each Norco package would equate to roughly 5 prescriptions (100 pills * 10 mg = 1000 MMEs, 1000 MMEs ÷ 210 MMEs = approximately 5 prescriptions). Rosenthal Report ¶¶ 94, 98–99.

¹² Expert Analysis: Lacey R. Keller, April 15, 2019 [hereinafter "Keller Report"] ¶ 55.

Keller backup materials show this chargeback being flagged by "doses_double_national_avg_flag" and "mme_double_national_avg_flag."

¹³ Keller Report ¶ 68.

Keller backup materials show this chargeback being flagged by "doses_actavis_ndc_order_flag."

dosage units being less than the total combined 300 dosage units of the September 2004 orders.

- The fourth chargeback, on March 2, 2006, reflects 1 Norco package totaling 100 dosage units, which would fill an average of 1 prescription. The fifth chargeback, on March 5, 2006, also reflects 1 Norco package totaling 100 dosage units, which would fill an average of 1 prescription. These chargebacks were jointly flagged by Ms. Keller's "common sense" metric, which is triggered if "prescriptions or orders within a rolling 30-day period were in excess of their maximum dosage units or frequency of transactions in any of the preceding six months."¹⁴
- This flagging appears to have occurred because the "frequency of transactions" exceeded the "maximum" in "the preceding six months." More specifically, Ms. Keller's algorithm identified *two* orders of 100 pills as an increase over the *one* order of 200 pills on September 12, 2005, despite both sets of transactions involving shipments of 200 total pills in the month.

Figure 5. Allergan chargeback transactions to pharmacies with transactions flagged by Ms. Keller

Buyer name	Date	Product	Qty	Dosage units	Est. Rx	Keller flag
CVS (Akron)	9/19/2004	Norco 10/325Mg	2	200	2	
CVS (Akron)	9/20/2004	Norco 10/325Mg	1	100	1	
CVS (Akron)	9/12/2005	Norco 10/325Mg	2	200	2	Actavis 125%
CVS (Akron)	3/2/2006	Norco 10/325Mg	1	100	1	Common sense
CVS (Akron)	3/5/2006	Norco 10/325Mg	1	100	1	Common sense
CVS (Stow)	8/28/2005	Norco 10/325Mg	6	600	6	Double National Average

Source: Keller backup materials; IQVIA data.

II.D. Allergan transactions in Cuyahoga and Summit counties account for only [REDACTED] of national Allergan transactions

- (13) In Figure 6, I present retail transactions for Kadian and Norco in Cuyahoga and Summit counties as a percentage of national retail transactions for Kadian and Norco, as found in Dr. McCann's processed

¹⁴ Keller Report ¶ 58.

Keller backup materials show these chargebacks being flagged by "chargebacks_common_sense_flag" but not "doses_common_sense_flag" or "mmes_common_sense_flag."

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ARCOS data. During the period 2006–2014, transactions of Kadian and Norco in Cuyahoga and Summit counties accounted for only [REDACTED] of national Kadian and Norco transactions.

Figure 6. Cuyahoga and Summit transactions as a percent of national transactions, by Allergan product

Year	Kadian	Norco	Total
[REDACTED]			

Source: McCann processed ARCOS data, 2006–2014.

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A handwritten signature in blue ink, appearing to read 'MK Kyle', is positioned above a horizontal line.

Margaret K. Kyle, PhD

June 27, 2019

Date

Appendix A. Additional materials considered

In addition to the materials listed here, I incorporate by reference all materials cited in Appendix B of my May 10 report and materials cited in this supplemental report.

- Deposition of Craig J. McCann, May 9, 2019.
- Deposition of Craig J. McCann, May 10, 2019.
- Deposition of Lacey Keller, June 13, 2019.
- Expert Analysis – Addendum: Lacey R. Keller, May 11, 2019.
- Expert Analysis – Errata Sheet: Lacey R. Keller, May 11, 2019.
- “Follow the Pill: Understanding the U.S. Commercial Pharmaceutical Supply Chain,” Prepared for The Kaiser Family Foundation by: The Health Strategies Consultancy LLC, March 2005.
- Keller backup data.
- McCann backup data.